

(3) The drug product is the subject of a notice of opportunity for hearing issued under section 505(e) of the Federal Food, Drug, and Cosmetic Act and published in the FEDERAL REGISTER on a proposed order of FDA to withdraw its approval for the drug product because it has determined that the product is less than effective for all its labeled indications.

(4) The drug product is presently not subject to a determination by FDA, made under its efficacy review program (see 21 CFR 310.6 for an explanation of this program), that there is a compelling justification of the drug product's medical need.

(b) FFP is not available in expenditures for the purchase or administration of any drug product that is identical, related, or similar, as defined in 21 CFR 310.6, to a drug product that meets the conditions of paragraph (a) of this section.

[46 FR 48554, Oct. 1, 1981]

§ 441.30 Optometric services.

The plan must provide for payment of optometric services as physician services, whether furnished by an optometrist or a physician, if—

(a) The plan does not provide for payment for services provided by an optometrist, except for eligibility determinations under §§ 435.531 and 436.531 of this subchapter, but did provide for those services at an earlier period; and

(b) The plan specifically provides that physicians' services include services an optometrist is legally authorized to perform.

§ 441.35 Organ transplants.

(a) FFP is available in expenditures for services furnished in connection with organ transplant procedures only if the State plan includes written standards for the coverage of those procedures, and those standards provide that—

(1) Similarly situated individuals are treated alike; and

(2) Any restriction on the practitioners or facilities that may provide organ transplant procedures is consistent with the accessibility of high quality care to individuals eligible for the procedures under the plan.

(b) Nothing in paragraph (a) permits a State to provide, under its plan, services that are not reasonable in amount, duration, and scope to achieve their purpose.

[56 FR 8851, Mar. 1, 1991]

§ 441.40 End-stage renal disease.

FFP in expenditures for services described in subpart A of part 440 is available for facility treatment of end-stage renal disease only if the facility has been approved by the Secretary to furnish those services under Medicare. This requirement for approval of the facility does not apply under emergency conditions permitted under Medicare (see § 482.2 of this chapter).

[43 FR 45229, Sept. 29, 1978, as amended at 51 FR 22041, June 17, 1986]

Subpart B—Early and Periodic Screening, Diagnosis, and Treatment (EPSDT) of Individuals Under Age 21

SOURCE: 49 FR 43666, Oct. 31, 1984, unless otherwise noted.

§ 441.50 Basis and purpose.

This subpart implements sections 1902(a)(43) and 1905(a)(4)(B) of the Social Security Act, by prescribing State plan requirements for providing early and periodic screening and diagnosis of eligible Medicaid recipients under age 21 to ascertain physical and mental defects, and providing treatment to correct or ameliorate defects and chronic conditions found.

§ 441.55 State plan requirements.

A State plan must provide that the Medicaid agency meets the requirements of §§ 441.56–441.62, with respect to EPSDT services, as defined in § 440.40(b) of this subchapter.

§ 441.56 Required activities.

(a) *Informing.* The agency must—

(1) Provide for a combination of written and oral methods designed to inform effectively all EPSDT eligible individuals (or their families) about the EPSDT program.

(2) Using clear and nontechnical language, provide information about the following—

(i) The benefits of preventive health care;

(ii) The services available under the EPSDT program and where and how to obtain those services;

(iii) That the services provided under the EPSDT program are without cost to eligible individuals under 18 years of age, and if the agency chooses, to those 18 or older, up to age 21, except for any enrollment fee, premium, or similar charge that may be imposed on medically needy recipients; and

(iv) That necessary transportation and scheduling assistance described in § 441.62 of this subpart is available to the EPSDT eligible individual upon request.

(3) Effectively inform those individuals who are blind or deaf, or who cannot read or understand the English language.

(4) Provide assurance to CMS that processes are in place to effectively inform individuals as required under this paragraph, generally, within 60 days of the individual's initial Medicaid eligibility determination and in the case of families which have not utilized EPSDT services, annually thereafter.

(b) *Screening.* (1) The agency must provide to eligible EPSDT recipients who request it, screening (periodic comprehensive child health assessments); that is, regularly scheduled examinations and evaluations of the general physical and mental health, growth, development, and nutritional status of infants, children, and youth. (See paragraph (c)(3) of this section for requirements relating to provision of immunization at the time of screening.) As a minimum, these screenings must include, but are not limited to:

(i) Comprehensive health and developmental history.

(ii) Comprehensive unclothed physical examination.

(iii) Appropriate vision testing.

(iv) Appropriate hearing testing.

(v) Appropriate laboratory tests.

(vi) Dental screening services furnished by direct referral to a dentist for children beginning at 3 years of age. An agency may request from CMS an exception from this age requirement

(within an outer limit of age 5) for a two year period and may request additional two year exceptions. If an agency requests an exception, it must demonstrate to CMS's satisfaction that there is a shortage of dentists that prevents the agency from meeting the age 3 requirement.

(2) Screening services in paragraph (b)(1) of this section must be provided in accordance with reasonable standards of medical and dental practice determined by the agency after consultation with recognized medical and dental organizations involved in child health care.

(c) *Diagnosis and treatment.* In addition to any diagnostic and treatment services included in the plan, the agency must provide to eligible EPSDT recipients, the following services, the need for which is indicated by screening, even if the services are not included in the plan—

(1) Diagnosis of and treatment for defects in vision and hearing, including eyeglasses and hearing aids;

(2) Dental care, at as early an age as necessary, needed for relief of pain and infections, restoration of teeth and maintenance of dental health; and

(3) Appropriate immunizations. (If it is determined at the time of screening that immunization is needed and appropriate to provide at the time of screening, then immunization treatment must be provided at that time.)

(d) *Accountability.* The agency must maintain as required by §§ 431.17 and 431.18—

(1) Records and program manuals;

(2) A description of its screening package under paragraph (b) of this section; and

(3) Copies of rules and policies describing the methods used to assure that the informing requirement of paragraph (a)(1) of this section is met.

(e) *Timeliness.* With the exception of the informing requirements specified in paragraph (a) of this section, the agency must set standards for the timely provision of EPSDT services which meet reasonable standards of medical and dental practice, as determined by the agency after consultation with recognized medical and dental organizations involved in child health

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care, and must employ processes to ensure timely initiation of treatment, if required, generally within an outer limit of 6 months after the request for screening services.

[49 FR 43666, Oct. 31, 1984; 49 FR 45431, Nov. 16, 1984]

§ 441.57 Discretionary services.

Under the EPSDT program, the agency may provide for any other medical or remedial care specified in part 440 of this subchapter, even if the agency does not otherwise provide for these services to other recipients or provides for them in a lesser amount, duration, or scope.

§ 441.58 Periodicity schedule.

The agency must implement a periodicity schedule for screening services that—

(a) Meets reasonable standards of medical and dental practice determined by the agency after consultation with recognized medical and dental organizations involved in child health care;

(b) Specifies screening services applicable at each stage of the recipient's life, beginning with a neonatal examination, up to the age at which an individual is no longer eligible for EPSDT services; and

(c) At the agency's option, provides for needed screening services as determined by the agency, in addition to the otherwise applicable screening services specified under paragraph (b) of this section.

§ 441.59 Treatment of requests for EPSDT screening services.

(a) The agency must provide the screening services described in § 441.56(b) upon the request of an eligible recipient.

(b) To avoid duplicate screening services, the agency need not provide requested screening services to an EPSDT eligible if written verification exists that the most recent age-appropriate screening services, due under the agency's periodicity schedule, have already been provided to the eligible.

§ 441.60 Continuing care.

(a) *Continuing care provider.* For purposes of this subpart, a continuing care

provider means a provider who has an agreement with the Medicaid agency to provide reports as required under paragraph (b) of this section and to provide at least the following services to eligible EPSDT recipients formally enrolled with the provider:

(1) With the exception of dental services required under § 441.56, screening, diagnosis, treatment, and referral for follow-up services as required under this subpart.

(2) Maintenance of the recipient's consolidated health history, including information received from other providers.

(3) Physicians' services as needed by the recipient for acute, episodic or chronic illnesses or conditions.

(4) At the provider's option, provision of dental services required under § 441.56 or direct referral to a dentist to provide dental services required under § 441.56(b)(1)(vi). The provider must specify in the agreement whether dental services or referral for dental services are provided. If the provider does not choose to provide either service, then the provider must refer recipients to the agency to obtain those dental services required under § 441.56.

(5) At the provider's option, provision of all or part of the transportation and scheduling assistance as required under § 441.62. The provider must specify in the agreement the transportation and scheduling assistance to be furnished. If the provider does not choose to provide some or all of the assistance, then the provider must refer recipients to the agency to obtain the transportation and scheduling assistance required under § 441.62.

(b) *Reports.* A continuing care provider must provide to the agency any reports that the agency may reasonably require.

(c) *State monitoring.* If the State plan provides for agreements with continuing care providers, the agency must employ methods described in the State plan to assure the providers' compliance with their agreements.

(d) *Effect of agreement with continuing care providers.* Subject to the requirements of paragraphs (a), (b), and (c) of this section, CMS will deem the agency to meet the requirements of this subpart with respect to all EPSDT eligible